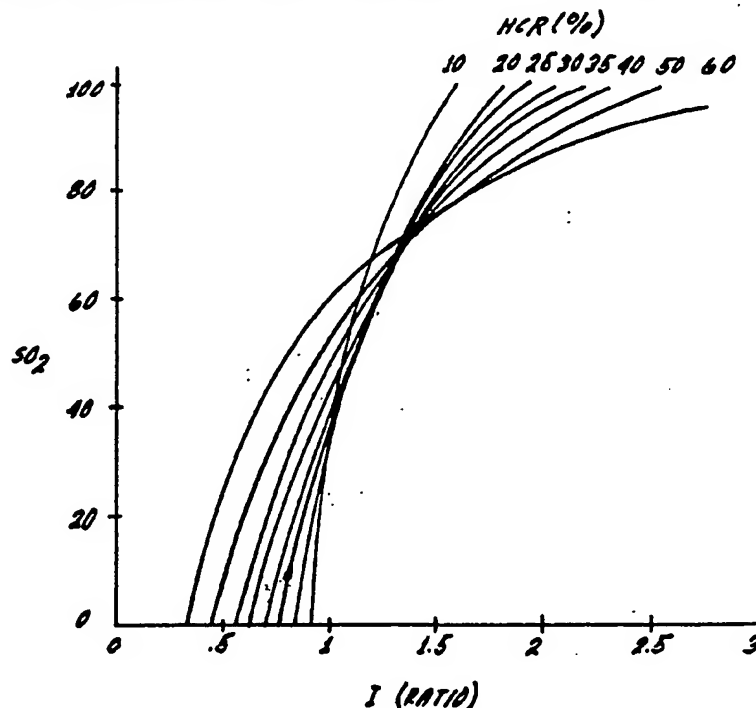




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: METHOD AND APPARATUS FOR DETERMINING OXYGEN SATURATION *IN VIVO*

(57) Abstract

Accurate *in vivo* measurement of blood oxygen saturation by fiberoptical means is made possible throughout a wide range of hematocrit or total hemoglobin values by using a single R/IR ratio I and calculating the SO<sub>2</sub> value therefrom through the use of a second-order polynomial of the form  $SO_2 = Ak^2I^2 + BkI + C$  in which A, B and C are hematocrit or total hemoglobin-dependent coefficients which may be contained in a lookup table accessed by a hematocrit or total hemoglobin value selection, and k is a purely multiplicative calibration constant which can be readily determined for any individual fiberoptic system.

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METHOD AND APPARATUS FOR DETERMINING  
OXYGEN SATURATION IN VIVO

Field of the Invention

5 This invention relates to the optical measurement of oxygen saturation in blood, and more particularly to a method and apparatus for providing a simpler and more accurate measurement than was previously possible.

10 Background of the Invention

Blood oxygen saturation ( $SO_2$ ) is conventionally measured in vivo by inserting a fiber optic catheter into a blood vessel and detecting the relative reflectivity of the blood under red and infrared illumination. 15 In one prior art device, an intensity ratio  $I = \frac{\lambda_2}{\lambda_1}$  was determined from a red intensity signal  $\lambda_1$  and in infrared intensity signal  $\lambda_2$ . A linear transfer function of the form  $SO_2 = BI + A$  was used to provide the saturation indication, with A being determined at the time of manufacture 20 and B being obtained by adjustment of a calibration knob after intubation to match an in vitro analysis of a blood sample taken from the patient. This method provided accurate information only at the saturation level at 25 which the sample was taken, and approximate information at all other levels.

Another prior art method (see U.S. Patent 4,114,604) used three intensity signals  $\lambda_1$ ,  $\lambda_2$ , and  $\lambda_3$  (typically on the order of 670, 700 and 800 nm respectively) from which 30 two ratios  $I_1 = \lambda_1/\lambda_2$  and  $I_3/\lambda_2$  were determined. The transfer function for the saturation indication was of the general form.

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$$SO_2 = \frac{A_0 + A_1 I_1 + A_2 I_3}{B_0 + B_1 I_1 + B_2 I_3}$$

or

$$SO_2 = \frac{A_0 + A_1 I_1 + A_2 I_1^2 + A_3 I_3}{B_0 + B_1 I_1 + B_2 I_1^2 + B_3 I_3}$$

in which the A and B factors were selectively weighted so as to minimize the effect of varying physiological characteristics of the blood under test. Calibration in this method involved both additive and multiplicative aspects of the optical measurements. Nevertheless, the transfer function of this method produced still only an approximation of the real  $SO_2$  values, particularly at hematocrits differing substantially from a nominal hematocrit of about 35%.

#### Summary of the Invention

The present invention uses only a single intensity ratio  $I = \lambda_1 / \lambda_2$  where  $\lambda_1 \approx 660$  nm and  $\lambda_2 \approx 810$  nm. The transfer function, however, is a second order polynomial of the general form

$$SO_2 = AI^2 + BI + C$$

in which A, B and C are hematocrit or total hemoglobin-dependent coefficients whose absolute values are different for different fiberoptic systems, but whose relation to one another remains constant for all systems. Consequently, the calibration of the inventive apparatus is a multiplicative operation only.

It is thus the object of the invention to provide a method and apparatus for accurately measuring blood oxygen saturation, in which the apparatus can be calibrated by a purely multiplicative operation.

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It is another object of the invention to achieve this result by using a transfer function having the form of a second order polynomial whose constants have a uniform proportionality to each other for all fiberoptic systems.

#### Brief Description of the Drawings

Fig. 1 is a tracking graph illustrating the effect of hematocrit (or total hemoglobin, which is generally directly proportional thereto) changes on the correspondence between calculated  $SO_2$  values and laboratory-determined  $SO_2$  values.

Fig. 2 is a ratio-saturation diagram showing the relation of blood oxygen saturation to the ratio  $\lambda_1/\lambda_2$  for various values of hematocrit.

Fig. 3 is a block diagram illustrating the signal processing in the inventive apparatus;

Fig. 4 is a coefficient-hematocrit diagram showing the values of A for various hematocrits;

Fig. 5 is a coefficient-hematocrit diagram showing the values of B for various hematocrits; and

Fig. 6 is a coefficient-hematocrit diagram showing the values of C for various hematocrits.

#### Description of the Preferred Embodiment

Blood oxygen saturation is typically measured by inserting a fiberoptic device into a blood conduit and positioning its tip at a point in the blood conduit where proper oxygen saturation is most critical. Light is transmitted to the distal tip through one fiber of the device, and the light reflected by the blood stream is returned to the outside of the body through the other fiber. The intensity of the reflected light at predetermined wavelengths in the red and infrared portions of the spectrum (preferably 660nm and 810 nm) is sensed by appropriate optoelectronic devices to provide the input signals to the oxygen saturation measuring instrument.

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Prior to intubation the fiberoptic system may be calibrated in vitro by measuring its response to a target of standard color and reflectivity.

Subsequently, the instrument may be calibrated  
5 in vivo by drawing a blood sample for laboratory analysis and relating a standard ratio derived from the laboratory oximeter value with the intensity ratio recorded at the time the blood sample was drawn.

If the instrument is properly calibrated and  
10 uses an accurate transfer function, the reading calculated from the red/infrared intensity ratio should match the laboratory oximeter at all saturation levels (line 10 in Fig. 1). However, this is not normally the case for two reasons. First, conventional instru-  
15 ments are sensitive to the hematocrit (HCT) of the blood and tend to track increasingly poorly as the hematocrit or total hemoglobin deviates from the generally accepted calibration level of 35% or 11.2 g/dl, respectively (lines 12, 14 of Fig. 1).

20 Unfortunately, sick patients tend to have hematocrits outside the normal range. In the vicinity of the calibration blood oxygen saturation level, in this example 70%, hematocrit changes have little effect, as shown by Fig. 1, but at materially different saturation levels, a significant error can occur with con-  
25 ventional instruments in a very sick patient.

The second tracking problem arises from the fact that the ratio/saturation curve not only changes with the hematocrit, but is also nonlinear. Prior art in-  
30 struments have either ignored the nonlinearity or have attempted to compensate for it in various ways by using complex transfer functions requiring, in some instances, more than two spectral intensity signals. In addition, the complexity of the prior art transfer  
35 function required the use of both multiplicative and

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additive operations to achieve calibration of individual fiberoptic systems.

The general operation of the apparatus of this invention is shown in Fig. 3. The red intensity signal is applied to input terminal 20, and the infrared intensity signal is applied to input terminal 22. Both signals are averaged over 50 ms intervals by filters 24, 26, respectively. The DC and AC components of the IR signal, and the DC component of the R signal, are then filtered individually by filters 28, 30, 32, respectively, to produce IR(DC), IR(AC), and R(DC) outputs averaged over half-second intervals. The purpose of the foregoing filtration is noise reduction by eliminating the effects of heartbeat and respiration.

The IR(DC) signal is averaged over 2-second intervals by filter 34 to produce a mean-IR output for purposes described in the copending application Serial No. 656,515 filed 01 October 1984, and entitled CARDIAC FLOW MONITOR. The IR(AC) signal is divided by the IR(DC) signal and then averaged over 2-second intervals by filter 36 to produce a cardiac flow monitor signal, again as described in the aforesaid copending application.

The filtered R(DC) signal is next divided by the filtered IR(DC) signal to produce the intensity ratio  $I=R(DC)/IR(DC)$ . The oxygen saturation level is calculated from this ratio, according to the present invention, through the use of a simple quadratic transfer function

$$SO_2 = Ak^2 I^2 = BkI + C$$

in which A, B, and C are hematocrit-dependent constants which may be contained in a look-up table 40 accessed by a laboratory-determined hematocrit selection 42.

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In the transfer function 38,  $k$  is a calibration constant which is determined for each individual fiber-optic system by in vitro or in vivo calibration as described above. In the latter case, the intensity ratio measured at the time of taking a blood sample from the patient is stored in a memory 46. After the sample has been analyzed by the laboratory, the value in memory 46 can be divided by a standard ratio computed on the basis of the sample's hematocrit and the look-up table 40 in a ratio former 47 so as to correspond to the laboratory-determined oximeter values in order to produce the calibration constant  $k$ . Alternatively, for in vitro calibration,  $k$  can be calculated by dividing the intensity ratio reflected by the calibration target and stored in memory 46 by the standard value of the calibration target.

The  $SO_2$  value calculated by using the transfer function 38 is next filtered by a damping filter 48 to prevent display flicker. The damped  $SO_2$  signal is then averaged over 2-second intervals by filter 50 to produce a mean  $SO_2$  value which can be displayed in display 44.

The hematocrit selection in the present invention is not automatic. However, hematocrit levels tend to change very slowly and (in a surgical environment) predictably. Consequently, the physician, knowing the effect the surgical procedure will have on the patient's hematocrit level, can either choose an average hematocrit setting or arrange for the hematocrit setting to be modified as the surgical procedure progresses.

Figs. 4, 5 and 6 show the values of the coefficients  $A$ ,  $B$  and  $C$  in accordance with this invention as a function of the hematocrit level. A look-up table such as 40 (Fig. 3) is a convenient tool for obtaining the greatest accuracy where it is most needed, for example by providing separate sets of coefficients at 1%



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intervals for the critical hematocrit levels lying between 10% and 30%, and at greater intervals in the less critical hematocrit ranges.

As will be seen from Fig. 2, the ratio-saturation  
5 curve for any given level of hematocrit is very closely parabolic in shape. Consequently, it is accurately expressible as a simple quadratic equation, and the ability of the present invention to adjust the co-  
efficients of the equation for individual hematocrit  
10 levels dispenses with the need for complex transfer functions.

In the preferred embodiment of the invention, the calculations leading to the determination of the  $SO_2$  value are performed by a microprocessor to which  
15 digitized R and IR signals are applied, and which can be appropriately programmed in accordance with conventional programming techniques. However, it should be understood that the invention is not so limited, and that the calculation of  $SO_2$  could also be carried out  
20 from analog input signals by conventional analog computing circuitry.

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CLAIMS

1. The method of measuring blood oxygen saturation in vivo comprising:

5 obtaining a pair of signals indicative of the reflectivity of the blood being measured in the red and infrared portions of the light spectrum, respectively;  
forming the ratio I of said signals;  
establishing the hematocrit level of said blood, and;

10 determining the oxygen saturation  $SO_2$  of said blood by the equation

$$SO_2 = Ak^2I^2 + BkI + C$$

15 in which A, B, and C are hematocrit-dependent coefficients and k is a calibration constant.

2. The method of claim 1 in which k is calculated by storing the value of said ratio at the time of taking a blood sample, ascertaining the actual saturation values of said sample in vitro, determining a standard value of said ratio corresponding to said actual saturation and hematocrit values, and making k equal to the ratio of said determined value to said stored value.

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3. Apparatus for measuring blood oxygen saturation in vivo, comprising:

optical means for illuminating blood within a blood conduit and providing a reflection therefrom;

5       sensing means for providing signals representative of the intensity of said reflection at a pair of wavelengths in the red and infrared portion of the spectrum, respectively;

divider means for forming the ratio I of said red to said infrared signals;

10       hematocrit selection means for selecting a hematocrit value corresponding to the hematocrit of said blood;

15       saturation determining means for determining an oxygen saturation value  $SO_2$  from said ratio in accordance with the transfer function

$$SO_2 = Ak^2I^2 + BkI + C$$

20       in which A, B, and C are hematocrit-dependent coefficients and in which k is a calibration constant; and

display means for displaying said determined  $SO_2$  value.

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4. The apparatus of claim 3 further comprising:  
memory means for storing the value of said ratio  
at the time of taking a blood sample;  
entry means for entering the actual SO<sub>2</sub> and  
5 hematocrit values of said sample;  
computing means for computing an intensity ratio  
corresponding to said SO<sub>2</sub> value; and  
quotient-forming means for forming the quotient  
of said computed ratio value to said stored value, said  
10 quotient being k.
5. The apparatus of claim 3 further comprising  
calibration means for calculating k so as to provide an  
SO<sub>2</sub> display consistent with the known SO<sub>2</sub> value of a standard  
reflector during in vitro calibration.
6. The apparatus of claim 3 further comprising  
look-up table means for storing the values of A, B and C  
for a plurality of hematocrit levels, said look-up table  
means being controlled by the selection of a hematocrit  
5 level at which blood oxygen saturation is to be measured.
7. The apparatus of claim 3 wherein A, B and C  
have uniform proportionality to each other for different  
systems.
8. The apparatus of claim wherein the absolute  
values of A, B and C decrease with increasing hematocrit.

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9 . The apparatus of claim 8 wherein the absolute value of B decreases more than the absolute values of A and C between 10% and 60% hematocrit.

10. The apparatus of claim 3 wherein the values of A, B and C vary with hematocrit values substantially in accordance with Figures 4, 5 and 6 hereof, respectively.

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Fig. 1

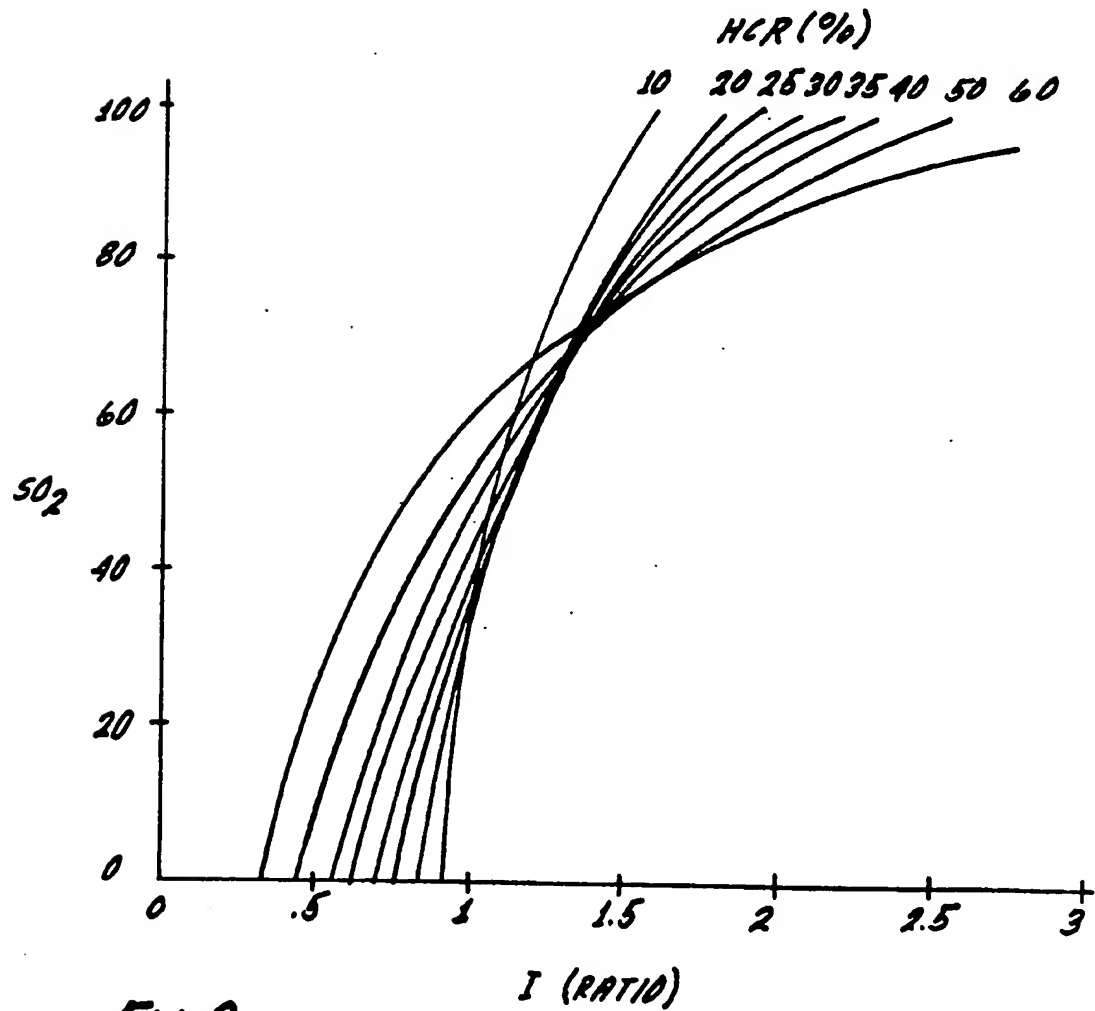
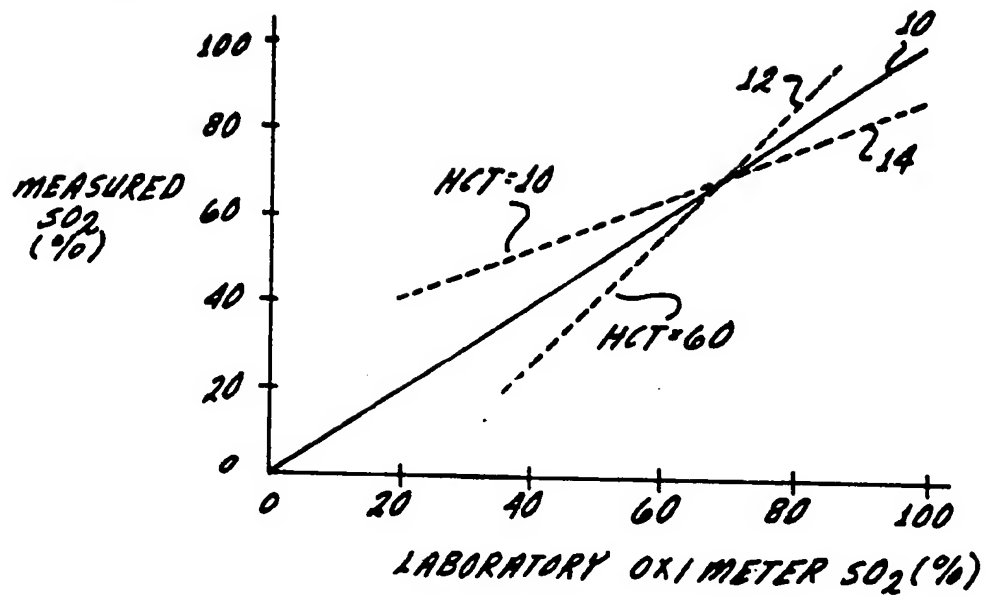


Fig. 2

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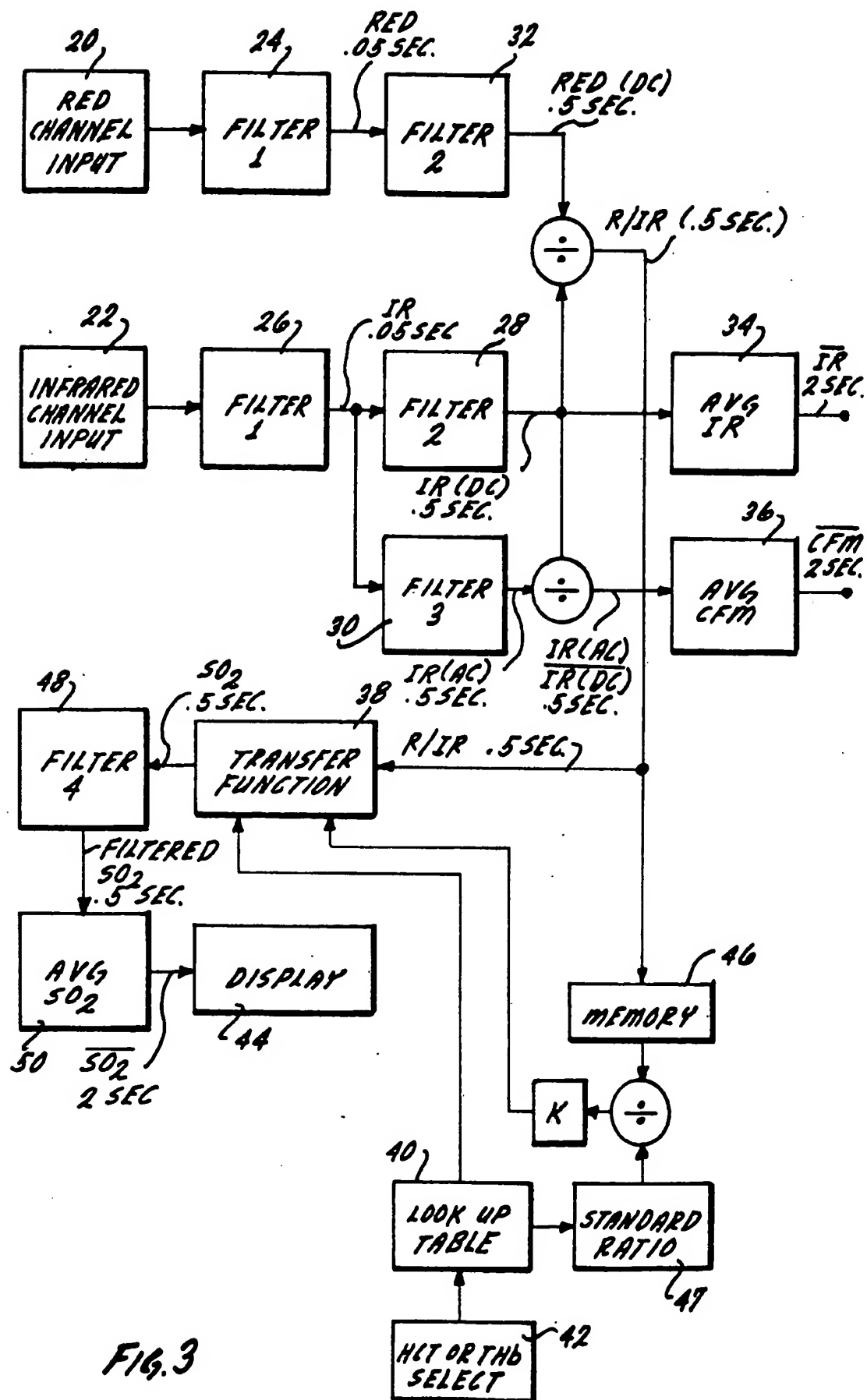
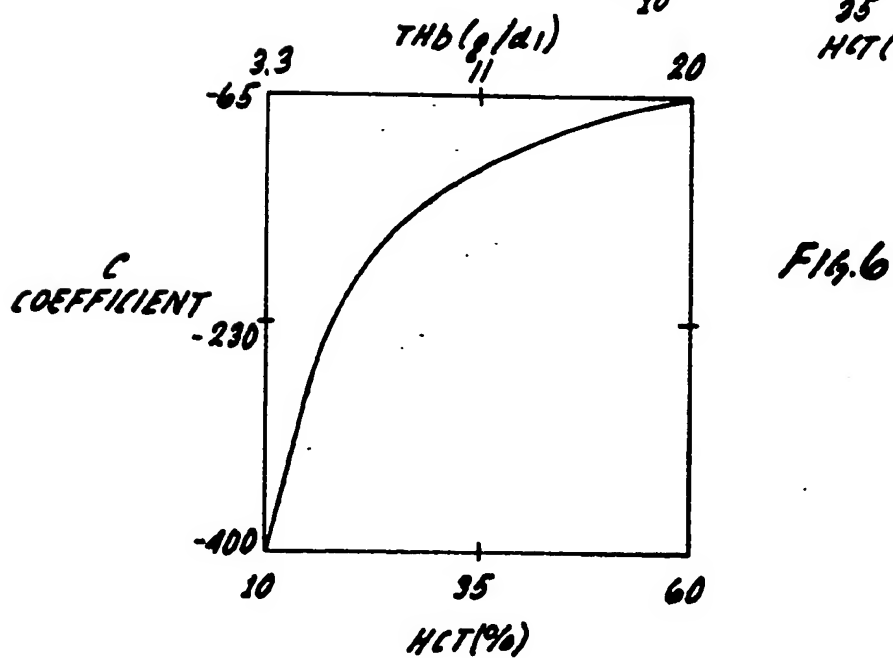
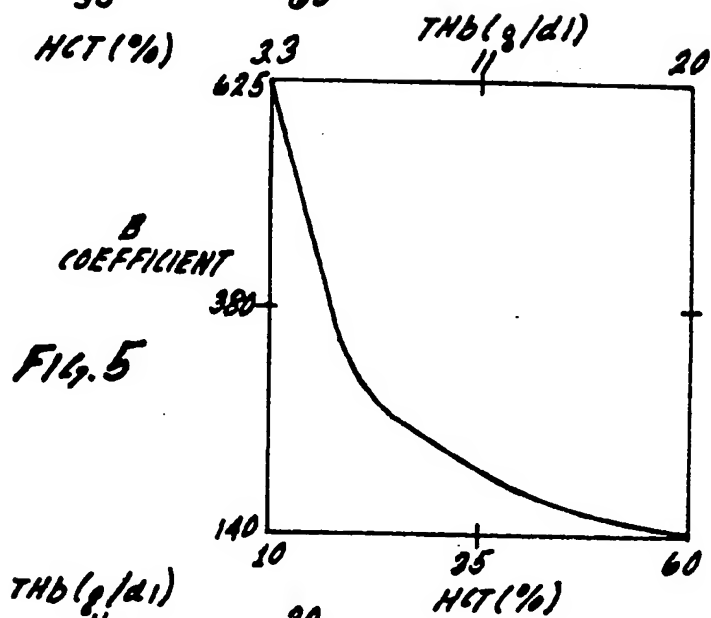
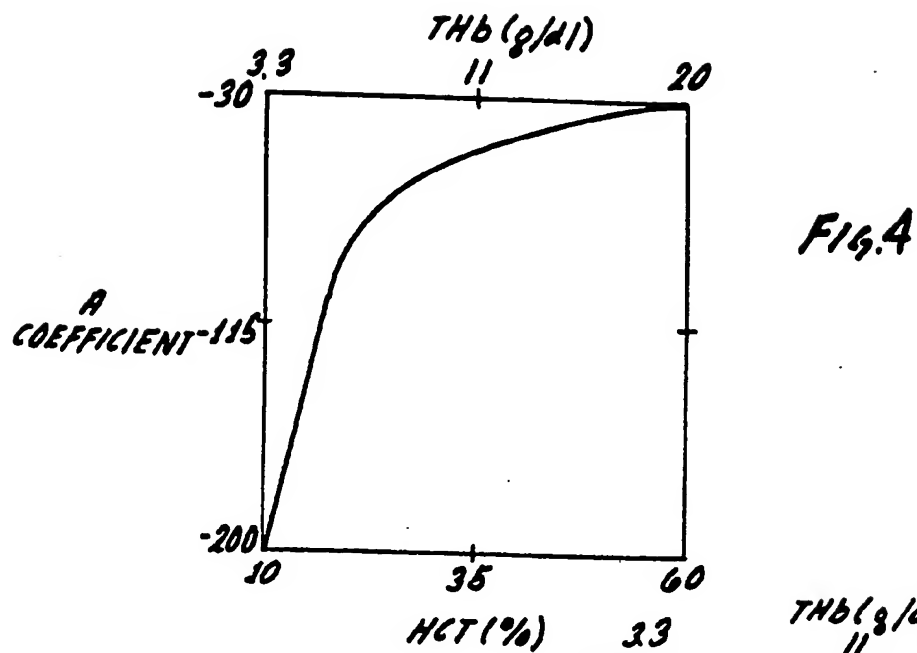



FIG. 3





# INTERNATIONAL SEARCH REPORT

International Application No PCT/US86/01146

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>3</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC <sup>(4)</sup> <b>CL. A61B 5/00; G01N 33/48</b> U.S. <b>CL. 128/633, 637; 356/41</b>		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>4</sup>		
Classification System	Classification Symbols	
U.S.	128/632, 633, 634, 637 356/39, 40, 41, 309	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>5</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>14</sup>		
Category <sup>6</sup>	Citation of Document, <sup>15</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No. <sup>18</sup>
A	US, A, 3,825,342 (Lubbers et al.) 23 July 1974	1, 3
A	US, A, 3,847,483 (Shaw et al.) 12 November 1974	1, 3
A	US, A, 4,114,604 (Shaw et al.) 19 September 1978	1, 3
A	US, A, 4,266,554 (Hamaguri) 12 May 1981	1, 3
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p><sup>*</sup> Special categories of cited documents: <sup>16</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Δ" document member of the same patent family</p> </div> </div>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search <sup>1</sup>	Date of Mailing of this International Search Report <sup>2</sup>	
7/23/86	05 AUG 1986	
International Searching Authority <sup>1</sup>	Signature of Authorized Officer <sup>20</sup>	
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